Clinical Policy: Buprenorphine-Naloxone (Bunavail, Cassipa, Suboxone, Zubsolv)

Reference Number: CP.CPA.299
Effective Date: 03.01.18
Last Review Date: 02.20
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Buprenorphine-naloxone (Bunavail®, Cassipa®, Suboxone®, and Zubsolv®) is a partial opioid agonist.

FDA Approved Indication(s)

Bunavail, Cassipa, Suboxone, and Zubsolv are indicated for the treatment of opioid dependence.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Bunavail, Cassipa, Suboxone, and Zubsolv are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid Dependence (must meet all)**:**

1. Diagnosis of opioid dependence;
2. Dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Suboxone: 24 mg/6 mg per day;
   c. Zubsolv: 17.1 mg/4.2 mg per day;
   d. Cassipa: 16 mg/4 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. Opioid Dependence (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. One of the following conditions is met (a or b):
   a. Member has NOT received an opioid analgesic since last approval;

b. Prescriber submits documentation acknowledging that the use of opioid during the last approval period was due to legitimate diagnosis of pain;

4. If request is for a dose increase, new dose does not exceed:
   a. Bunavail: 12.6 mg/2.1 mg per day;
   b. Suboxone: 24 mg/6 mg per day;
   c. Zubsolv: 17.1 mg/4.2 mg per day;
   d. Cassipa: 16 mg/4 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Pain management;

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to buprenorphine or naloxone
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Suboxone) sublingual (SL) or buccal dissolving film	Induction: Titrate to 8 mg/2 mg SL on Day 1 and 16 mg/4 mg SL on Day 2; then start maintenance treatment Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day

Drug Name	Dosing Regimen	Maximum Dose
Buprenorphine-naloxone (Bunavail) buccal film	Maintenance: Target dose: buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments or decrements of 2.1 mg/ 0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 12.6 mg/2.1 mg per day	12.6 mg/2.1 mg per day
Buprenorphine-naloxone SL tablet	Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	24 mg/6 mg per day
Buprenorphine-naloxone (Zubsolv) SL tablet	Induction: Titrate to 5.7 mg/1.4 mg SL on Day 1 and 11.4 mg/2.9 mg SL on Day 2; then start maintenance treatment Maintenance: Target dose: buprenorphine 11.4 mg/naloxone 2.9 mg once daily; dosage should be adjusted in increments or decrements of 2.9 mg/ 0.71 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.9 mg/0.71 mg to 17.1 mg/4.2 mg per day	17.1 mg/4.2 mg per day
Buprenorphine-naloxone (Cassipa) SL film	Maintenance: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be titrated to target dose using another marketed product (Cassipa comes in a single dose and cannot be adjusted)	16 mg/4 mg per day

VI. Product Availability

Drug Name	Availability
Buprenorphine-naloxone (Suboxone)	Sublingual film: buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg
Buprenorphine-naloxone (Bunavail)	Buccal film: buprenorphine/naloxone 2.1 mg/0.3 mg; 4.2 mg/0.7 mg, 6.3 mg/1 mg
Buprenorphine-naloxone	Sublingual tablet: buprenorphine/naloxone 2 mg/0.5 mg, 8 mg/2 mg
Buprenorphine-naloxone (Zubsolv)	Sublingual tablet: buprenorphine/naloxone 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg /0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg
Buprenorphine-naloxone (Cassipa)	Sublingual film: buprenorphine/naloxone 16 mg/4 mg

VII. References

1. Suboxone Sublingual Film Prescribing Information. North Chesterfield, VA: Indivior Inc.; October 2019. Available at: https://www.suboxone.com/. Accessed November 26, 2019.
2. Bunavail Prescribing Information. Raleigh, NC: BioDelivery Sciences International, Inc.; October 2019. Available at: https://bdsi.com/bunavail/. Accessed November 26, 2019.
3. Zubsolv Prescribing Information. Morristown, NJ: Orexo US, Inc.; October 2019. Available at: https://www.zubsolv.com/. Accessed November 26, 2019.
4. Cassipa Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208042s000lbl.pdf. Accessed November 26, 2019.
5. Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2004. (Treatment Improvement Protocol (TIP) Series, No. 40.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK64245/. Accessed October 23, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created - Policy split from CP.CPA.276 Buprenorphine, Buprenorphine plus Naloxone (retired). - Initial: removed requirement that member is not using concurrent opioid medications (including tramadol). - Re-auth: added requirement related to absence/presence of opioid use since last approval; - Modified initial/continued approval duration from LOB to 12 months due to potential for abuse. - Added pain management as a diagnosis for which coverage is not authorized. - References reviewed and updated.	11.08.17	02.18
1Q 2019 annual review: no significant change from previously approved policy; references reviewed and updated.	10.23.18	02.19
RT4: added new dosage form Cassipa to the policy.	06.21.19	
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and

accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.